**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| APPLICANT: | Christopher T. Boyle | CUSTOMER NO. | 29,335 |
| SERIAL NO.: | 09/716,146 | Examiner: | C. Miller |
| Filed: | 11/17/2000 | Art Unit: | 3738 |

Title: DEVICE FOR IN VIVO DELIVERY OF BIOACTIVE AGENTS AND METHOD OF MANUFACTURE THEREOF

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**SUBMISSION OF APPELLANT'S BRIEF ON APPEAL**

Dear Sir or Madam:

Appellant submits herewith Appellant's Brief on Appeal. The Commissioner is authorized to deduct the required fee for filing an Appeal Brief in the amount of $515.00 which includes a two month extension fee from Deposit Account 18-2000, of which the undersigned is an authorized user. Accordingly, Appellant does not believe any additional fees are due in the Appeal Brief; however, the Commissioner is authorized to charge any additional fees regarding this filing, and/or credit any overpayment to deposit account No. 18-2000.

# APPELLANT'S BRIEF ON APPEAL

## 1. Real Party Interest

The real party interest for this patent application is Advanced Bio Prosthetic Surfaces, Ltd., the assignee of the application.

## 2. Related Appeals and Interference

Board Decision in present application 09/716,146 decided on April 30, 2008, Appeal No. 2007-3212.

Board Decision for related U.S. Application 09/707,685 decided on September 29, 2008, Appeal 2008-1316 (hereinafter the '685 Board Decision").

Board Decision for related U.S. Application 09/783,633 decided on February 21, 2008, Appeal No. 2008-0216.

Board Decision for related U.S. Application 10/672,695 decided on March 31, 2009, Appeal No. 2008-5417.

Board Decision for related U.S. Application 10/258,087 decided on December 20, 2008, Appeal No. 2008-1062

## 3. Status of Claims

Claims 16, 20, 26-28 are finally rejected under 35 U.S.C. §103(a) as being unpatentable over Brown et al., U.S. Patent No. 6,071,305 in view of Whicher et al., U.S. Patent No. 6,938,668. The rejection of each claim is under appeal.

## 4. Statement of Amendments

No amendments have been filed after the issuance of the final rejection.

## 5. Summary of the Claimed Subject Matter

Claim 16 is the sole independent claim pending in the application. Antecedent support for each element in Claim 16 is noted in the parentheses following each claim element:

An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of vacuum deposited structural elements (Page 5, lines 1-2; Page 10, lines 19-20; Page 11, lines 2-12) forming a radially expandable cylindrical member (Page 6, lines 26-30; Page 7, lines 4-6), the plurality of structural vacuum deposited elements including a complex

finished geometry (See, e.g., Figures 2, 5, 8; Page 8, lines 29-31), each of the plurality of vacuum deposited structural elements having a wall thickness (See, e.g., Figures 3-4; Figures 6-10; Page 10, lines 11 and 23); wherein the vacuum deposited structural elements are fabricated of a metal (Page 8, lines 23-26) and comprise a base layer (Page 11, lines 8-11) and a second layer covering the base layer (Page 11, lines 11-12), further comprising a void space intermediate the base and second layers that is enclosed therebetween (Page 11, lines 12-13);

a plurality of pores passing through the second layer and communicating with the void space such that the void space is open only through the plurality of pores (Page 7, line 3 – Page 8, line 16; Page 10, lines 8-15; Page 11, lines 12-13); and

at least one bioactive agent retained within the void space and elutable through the plurality of pores (Page 8, lines 4-16).

## 6. Grounds of Rejection to be Reviewed on Appeal

I. *Claims 16, 20, 26-28, and 30-37 are rejected under 35 U.S.C. §103(a) as being unpatentable over by Brown, et al., U.S. Patent No. 6,071,305 in view of Whicher et al., U.S. Patent No. 6,938,668.*

Regarding Applicant's Claim 16, the Examiner has taken the position that Brown discloses an endoluminal stent for delivering a bioactive agent (col. 1, lines 12-20) comprising a plurality of structural elements (12; although only one structural element is shown in Figs. 1 and 2, the Examiner argues that a plurality of structural elements 12 are disclosed as additional possible embodiments at col. 7, lines 34-39; mesh stent, each filament of the plurality of filaments in the mesh being a structural element 12), the structural elements (12) forming a complex geometry (other configurations such as coiling stents, expandable tube stents, roving wire stents, and wire mesh stents, col. 7, lines 34-40), each structural element (12) having a wall thickness (cross sectional thickness of an element 12 as seen in Figs. 3-10) and fabricated from metal (col. 7, lines 11-18) comprising a base layer (considered surface or layer 18) and a second layer (considered abluminal surface or layer 19) covering the base layer (see Figs. 2A, 3, 6, 8 and the Examiner's Attachments 2-5 which more clearly show the location of the "layers"), a void space (20) intermediate the layers and enclosed therebetween, a plurality of pores (22, 28, 54) passing through the second layer (19), such that the void space is only open through the pores (see, e.g., Figs. 3 and 6), and at least one bioactive agent (23; col. 5, lines 1-27).

Regarding the term "layer," the Examiner argues that layer may be considered a portion/thickness/layer of the stent strut (12). The Examiner argues that Applicant's only

recitation of the word layer is referral to a deposition process, in which layer upon layer is deposited until forming one unitary device (as shown in Applicant's Figures). The Examiner argues that Applicant's claims refer to a stent which is shown in Applicant's Figs. 2-7, which contains structural elements 21 or 31 shown generally cylindrical, having a longitudinal axis (as shown in Fig. 7) and a round cross-section (as shown in Fig. 3 and 6; Fig. 6 shows two adjacent structural elements). The Examiner argues that the "layers" are not clearly pointed out in the Figures as the specification only refers to "layers" as depositing layer upon layer to form the device shown in the Figures. The Examiners states that it is unclear where one layer starts and ends, but it would appear Applicant is referring to an abluminal and luminal "layer" (referenced as elements 26, 28, 33, and 35).

In support of the argument that Brown's structural elements 12 comprise "layers," the Examiner argues that Brown has shown the same type of structural elements 12, each having a generally round cross-section (Figs. 3-10; which also may be alternately cross-sections, such as a square, col. 6, lines 1-5 which would form flat planar layers) with an inner void space 20. The Examiner argues that, structurally, the elements of Brown are the same as the Applicant's (compare Fig. 2A of Brown to Fig. 7 of Applicant; compares Fig. 3, 6, and 8 of Brown to Fig. 6 of Applicant, keeping in mind that Applicant's Fig. 6 shows two side by side structural elements; see Examiner's Attachments 1-5). The Examiner argues that the structural elements of Brown and Applicant are the same. Therefore, the Examiner argues that a "layer" of Applicant's structural element also may be considered a "layer" of Brown's structural element (see Examiner's Attachments, wherein the second layer is shown shaded to distinguish it from the base layer, both layers being part of structural element 12 which is fully made of metal, both layer are metal).

The Examiner states that although Brown discloses Applicant's claimed endoluminal stent, Brown does not disclose vacuum deposition metal to form the structural elements (i.e. a method of manufacture). The Examiner states that Brown is silent to mention any method of manufacture for stent 11 (the only methods disclosed are for the embodiment in Fig. 17, which is a different embodiment, and a method shown in Figs. 13-18 and col. 11, lines 62-67, which is disclosed as cutting by laser or other conventional cutting means). The Examiner argues that Whicher teaches in the same field of endoluminal stents, a method of making a stent by using vacuum deposition techniques (col. 3, line 52 – col. 4, line 30) as an improvement over older techniques such as cutting and etching etc. (col. 1, lines 31-51; cutting being the only type

mentioned by Brown), in order to improve the properties of the material (discloses control of microstructure, col. 2, lines 6-9; col. 3, lines 18-25; also Whicher discloses the same method of manufacture, vacuum deposition, Whicher process will inherently produce microstructure and heterogeneities, since such control over properties are characteristic of such a process). The Examiner argues that it would have been obvious to one having ordinary skill in the art at the time invention was made to combine Brown's endoluminal stent shape, with Whicher's method of manufacture (vacuum deposition) in order to provide a stent with improved material properties).

The Examiner disagrees with Applicant's argument that Whicher does not teach a plurality of vacuum deposited structural elements including a complex finished geometry. The Examiner argues that both Brown and Whicher disclose stents of complex geometry (see Brown col. 7, lines 34-39, each "structural element" being a strut (12) and the complex geometry being the "expandable tube stents, roving wire stents, and wire mesh stents"). The Examiner argues that Whicher also discloses complex geometries that are vacuum deposited (tailor geometries, col. 3, lines 15-25; col. 6, lines 21-57; Figs. 2 and 3).

Regarding Applicant's Claim 20, the Examiner argues that Brown discloses a degradable plug (biodegradable matrix 27 which is shown in the cavities and extending into the pores as seen in Figs. 3 and 9 for example; col. 8 line 62 – col. 9 line 5).

Regarding Applicant's Claim 26, the Examiner argues that Brown discloses a stent having structural elements comprising a material selected from the group claimed (col. 7, lines 12-18).

Regarding Applicant's Claim 27, the Examiner states that Brown discloses a bioactive agent selected from the group claimed (col. 5, lines 1-27).

Regarding Applicant's Claim 28, the Examiner states that Brown discloses a void space comprising a plurality of independent internal cavities along the length of the structural elements (each structural element 12 in the mesh stent may have its own cavity, thus plurality of cavities amongst all the structural elements 12; further, elements 12 are shown to have multiple cavities Fig. 9, for example; further, at least one cavity is disclosed, encompassing more than one, col. 2, lines 59-61).

Regarding Applicant's Claims 30-37, the Examiner argues that Whicher clearly discloses controlling properties of the material and its microstructure (heterogeneities) by the deposition process (col. 2, lines 6-10 and 16-31; col. 3, lines 17-25; see also Board Decision for related U.S.

Application 09/707,685 mailed on September 30, 2008 having a common inventor, same assignee, and same attorney of record in which the Whicher reference was affirmed based on similar claim language). The Examiner argues that Whicher's method inherently controls the stent's heterogeneities because Whicher discloses the same vacuum deposition processes (sputtering, ion beam deposition) and use of the same materials used by the Applicant. The Examiner states that Applicant discloses in its specification that it is the vacuum deposition process that controls the heterogeneities. The Examiner argues since Whicher is using the same process as the applicant, Whicher is inherently "controlling heterogeneities" just as much as the Applicant. The Examiner further argues that Whicher discloses controlling the microstructure (see col. 2, lines 15-32; col. 3, lines 15-25; and Board Decision of related U.S. Application 09/707,685 mailed on September 30, 2008).

## 7. Argument

The Examiner has failed to establish a *prima facie* case of obviousness with respect to Claim 16, because neither Brown nor Whicher, either alone or in combination, teach or suggest Claim 16's limitation of a base layer and a second layer covering the base layer. Additionally, the Examiner has failed to establish a *prima facie* case of obviousness with respect to Claim 16, because neither Brown nor Whicher, either alone or in combination, teach or suggest Claim 16's limitation of a void space intermediate the base and second layers that is enclosed therebetween. And even if Brown and Whicher, either alone or in combination, teach or suggest each of Claim 16's elements, the obviousness rejection is improper because the Examiner has not provided explicit analysis of why it would have been obvious to combine the elements of Brown and Whicher in the manner of Claim 16, nor has the Examiner proffered support in the references themselves that supports any motivation for one skilled in the art to apply the process technology of Whicher to fabricate the device of Brown. Simply put, there is nothing in Brown that would suggest that it is susceptible of manufacture by the vacuum deposition processes of Whicher to form the device claimed in the present application. And even if there is a reason to combine the elements in Brown and Whicher, such a hypothetical construct would not have been predictable to one of ordinary skill in the art at the time the invention was made.

Furthermore, the obviousness rejection of Claim 20 is legally insufficient given that Brown and Whicher's fail to teach or suggest, in combination, the claimed elements of "a degradable plug residing within the plurality of pores to prohibit release of the at least one

bioactive agent until the degradation of the degradable plug." Also, the Examiner has failed to establish a *prima facie* case of obviousness with respect to Claim 28, because neither Brown nor Whicher, either alone or in combination, teach or suggest Claim 28's limitation of a plurality of a plurality of independent internal cavities along the length of the structural elements. Finally, the Examiner has failed to establish a *prima facie* case of obviousness with respect to Claim 30 because neither Brown nor Whicher, either alone or in combination, teach or suggest, inherently or explicitly, Claim 30's limitation of a stent having at least one surface having controlled heterogeneities thereupon.

## I. The Examiner's obviousness rejection of Claim 16 under 35 U.S.C. §103(a) is improper and should be withdrawn.

In order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03; *In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974). The Examiner has failed to establish a *prima facie* case of obviousness with respect to Claim 16 because neither Brown nor Whicher, either alone or in combination, teach or suggest Claim 16's limitations of a base layer and a second layer covering the base layer or a void space intermediate the base and second layers that is enclosed therebetween. Furthermore, in the **precedential** BPAI Decision *Ex parte Whalen*, the Board held that "obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some 'apparent **reason** to combine the known elements in the fashion claim.'" BPAI Appeal 2007-4423, p. 16 (July 23, 2008) (quoting *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007)), emphasis added. Therefore, even if Brown and Whicher, either alone or in combination, teach or suggest each of Claim 16's elements, the obviousness rejection is improper because neither Brown nor Whicher provides a reason to combine their elements in the manner of Claim 16.

Claims 20, 26-28, and 30-37 depend from independent Claim 16. These claims are allowable for the same reasons set forth with respect to their parent Claim 16 since each sets forth additional elements of Applicant's device, as indicated below. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious under 35 U.S.C. §103(a), the claims dependent therefrom are also nonobvious).

### A. Brown fails to disclose a base layer and a second layer

Previously, the Board held:

> Brown does not describe a stent with a metal base layer and a second layer also made of metal, wherein the base and the second layers enclose a void space containing an active agent, and therefore, does not anticipate the claimed invention.

*Ex parte Boyle*, Appeal 2007-3231, p. 13 (April 30, 2008). Applicant submits that this previous holding by the Board is sufficient to prove that Brown fails to disclose Claim 16's elements of a base layer and a second layer. Nevertheless, the Examiner argues that this Board holding is irrelevant since "the second layer was considered by the Examiner to be [Brown's elements] 34, 44, and 49" (Final Office Action mailed February 2, 2009, page 2), whereas, instantly, Examiner considers Brown's elongated member 12 to be composed of a base and second layer. Although Applicant believes the Board's previous holding resolves the issue of whether Brown discloses a base and second layer, Applicant will assume, *arguendo*, that the Board's previous holding is irrelevant and will address the Examiner's arguments directly.

The Examiner construes the term "layer" as a "portion/thickness/layer of [Brown's] stent strut (12)." (Final Office Action mailed February 2, 2009, page 2). The Examiner asserts that Brown discloses "structural elements (12)... comprising a base layer (considered luminal surface or layer 18) and a second layer (considered abluminal surface or layer 19) covering the base layer (see figures 2A, 3, 6, 8 and attachments 2-5 which more clearly show location of "layers")." (Final Office Action mailed February 2, 2009, page 4). In support of this assertion, the Examiner compares Brown's Fig. 2A to Applicant's Fig. 7 and Brown's Figs. 3, 6, and 8 to Applicant's Fig. 6 (as shown in Examiner's Attachments 2-5 wherein the Examiner has shaded Brown's figures to distinguish a second layer from a base layer).

First, Applicant respectfully disagrees with the Examiner's definition of the term "layer" as being a "portion/thickness/layer of [Brown's] stent strut [i.e. elongated member] (12)." To begin with, any term should not be defined with reference to the term itself. Accordingly, Applicant will assume that Examiner understands the term "layer" to be "a portion/thickness of" Brown's elongated member 12, even though the term "layer" should be construed according to the Applicant's specification.

Claim 16 requires discrete layers: "**a** base layer and **a** second layer covering the base layer." Since "discrete" merely means "apart or detached from others," then the layers are naturally "apart or detached from each other," or more simply put, separate claim elements of Claim 16. Such a claim construction is necessary to give meaning to the "void space intermediate the base and second layers and enclosed therebetween" limitation. The layers have

to be discrete, i.e. apart or detached from each other, in order to have the void space intermediate and enclosed therebetween the second layer and the base layer. Therefore, the base layer and second layer are not a portion/thickness of any element, as the Examiner contends.

Moreover, during patent examination, the pending claims must be "given their broadest **reasonable** interpretation consistent with the specification." [Emphasis added] *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000). In order to manufacture Applicant's endoluminal stent, Applicant's specification states that internal cavities and openings can be formed by depositing patterned sacrificial material "over a base layer of structural material, then depositing a second layer of structural material over the sacrificial material and the base layer" and removing the sacrificial material "to leave the internal cavities and plurality of openings." (Spec. page 11, lines 8-13). The Board previously determined this statement to be a "Finding of Fact." *Ex parte Boyle*, Appeal 2007-3231, p. 3 (April 30, 2008) (see FF3). Given that a "sacrificial material" may be disposed between the base and second layer, interpreting Claim 16's "layers" as being apart or detached from each other is a reasonably broad interpretation consistent with the specification. As such, the base layer and second layer cannot be a portion or thickness of another element as the Examiner contends.

In contrast, the Examiner's "layer" of "a portion/thickness of" an object is not apart or detached from other portions/thicknesses of the object. The "portion/thickness of" an object is a limited part of the entire object. Still further, "a portion/thickness of" an object is likely integrally formed with other portions/thicknesses of the object. Thus, "a portion/thickness" is not the same as the discrete base and second layers required by Claim 16.

Second, the Examiner's misconstruction of the term "layer" results in the Examiner's erroneous redrawing of Brown's Figs. 2A, 3, 6, and 8 (as seen in Attachments 2-5) wherein the Examiner adds a "base layer" and "second layer" to Brown's elongated member 12 to inappropriately reconstruct Claim 16. The "base layer" and "second layer" denoted by the Examiner in Attachments 2-5 may be portions/thicknesses of Brown's elongated member 12; however, they are not the same as the discrete base and second layers required by Claim 16. Nowhere in Brown's application is the elongated member 12 described as being composed of layers. On the contrary, Brown's elongated member 12 is described as being manufactured from "**a** strand, filament or fiber" (Brown col. 5, lines 65-67), emphasis added. The strands, filaments, and fibers in Brown's Figs. 2A, 3, 6, and 8 have a cross-section of a numerous thicknesses to make a circular, elliptical, octagonal, or square shape as to not be a base layer and a second layer

covering the base layer. Naturally, a layer does not have a circular, oval, elliptical, or octagonal cross sectional shape, because such a cross sectional shape results in a wholly different structure with different structural capacities and limitations. As such, a strand, filament, or fiber of elongated member 12 would not be a layer as construed by a person of ordinary skill in the micro-electronics fabrication arts, as required in the claim construction for Claim 16. Regardless of how creative an Examiner may be, prior art patents and drawings must be interpreted for what they reasonably convey to an ordinary artisan and not be construed through hindsight reconstruction of applicant's disclosure.

Still further, Brown states a single, continuous material as to not include separate discrete base layer and second layer, as follows:

> The elongated member 12 is preferably formed of **a** fairly rigid, impermeable, and strong material which is non-biodegradable. The elongated member material is preferably **a** biocompatible metal or alloy such as stainless steel, titanium, platinum, tantalum, silver, tungsten, gold, and their alloys as well as gold-plated ferrous alloys, platinum-plated ferrous alloys, cobalt-chromium alloys and titanium nitride coated stainless steel. Alternatively, the elongated or tubular member 12 may be formed of **a** polymer, such as polyether sulfone, polyamide, polycarbonate, polypropylene, high molecular weight polyethylene, carbon fiber, and the like.

(Brown, Col. 7, lines 12-21), emphasis added. Brown's reference to the composition of the elongated or tubular member 12 clearly indicates that it is **a** singular, continuous substance. Thus, the Examiner's alteration of Brown's Figs. 2A, 3, 6, and 8 to include a base and second layer is unwarranted.

More so, Applicant recognizes that Brown's Figs. 2A, 3, 6, and 8 each include lines that seemingly separate the elongated member 12 into individual sections. However, Brown does not label any of the individual sections formed by these lines nor does Brown describe the elongated member 12 as having individual sections in the specification. One of ordinary skill in the art immediately recognizes the lines in Brown's Figs. 2A, 3, 6, and 8 are "sectional lines" commonly used by draftsmen to denote that a cross-sectional view is being shown (this drafting technique is also known as "hatching"). Brown's Figs. 2A, 3, 6, and 8 are described in the "BRIEF DESCRIPTION OF THE DRAWINGS" as being "sectional" or "cross-sectional views," which supports the view that lines are sectional lines. Even if these lines are not considered "section lines," the Examiner inappropriately groups several sections together and labels them as a base layer or a second layer. For example, in the Examiner's redrawing of Brown's Fig. 6 in Attachment 3 (reproduced below), the Examiner arbitrarily shades three of the

sections of elongated member 12 and labels them as the second layer and then labels the remaining four sections as the base layer.

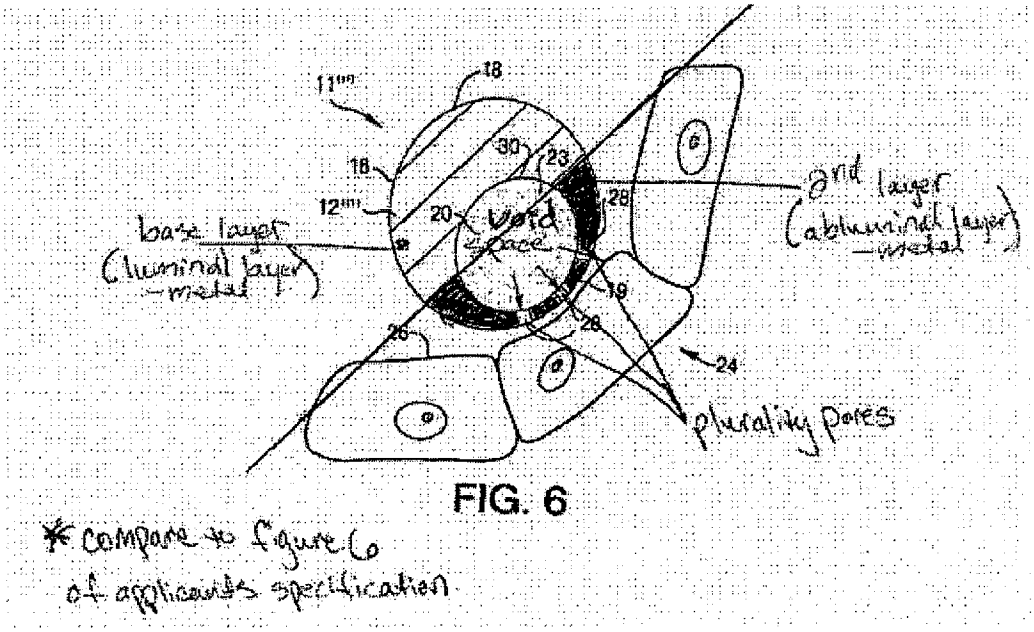



FIG. 6

* compare to figure 6a of applicants specification

If Brown's Fig. 6 were properly depicting Claim 16's base layer and second layer, then Fig. 6 would show only two sections – one section relating to a base layer and one section relating to a second layer. And while the cross-section may be oval, elliptical, octagonal, or square, the cross-section will still remain a single strand, filament, or fiber, nothing more. Thus, the Examiner's redrawing of Brown's Fig. 6 in Attachment 3 is arbitrary and unwarranted.

Most importantly, the Examiner construes Claim 16 through a figure-by-figure comparison of Applicant's figures with Brown's figures. the Examiner compares Brown's Fig. 2A to Applicant's Fig. 7 and Brown's Figs. 3, 6, and 8 to Applicant's Fig. 6. The Board is obligated to construe claims broadly as it reasonably can, but the reasonable limits of that breadth are set by the plain language of the claims and the teachings of the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). The Examiner's figure by figure comparison of the present application and Brown lends itself to misconstruing the claims and departing from the claim language. The reasonable limits of the meaning of "layer" are set by the teachings of the present application with reference to the vacuum deposition techniques described in the specification. Yet, the Examiner continually takes the elements in Brown, which the Examiner acknowledges are not vacuum deposited metal, to form the limitations of the independent claim 16. Such construction is without reasonable limits.

And the Applicant notes that Figures 5-7 of the present application illustrate an alternative embodiment of the invention. However, Figure 1, Figures 2-4, and Figures 8-10 all illustrate alternative embodiments of the invention; yet, the Examiner conveniently only uses Figures 6 and 7 as a comparison to Brown's Figs. 2A, 3, 6, and 8. Applicant's specification clearly delineates different embodiments of the invention, with different methods for making each different embodiment. One embodiment and its associated method, entails forming the device by employing pre-formed microtubules. A second embodiment and its associated method entails forming the claimed device by vacuum depositing the metal structural members and forming the first and second layers of metal structural members and the intermediate void space during the deposition process. (Specification, Page 10, line 20 – Page 11, line 13). Claim 16's plurality of structural vacuum deposited elements comprise base layer and second layer covering the base layer is drawn to vacuum deposition embodiment of the invention, and not merely to Figures 5-7 of the present application. As such, the Examiner's construction and interpretation of Claim 16's limitation in view of Applicant's Figures 5-7 is misplaced and in error.

Analyzing figure-by-figure, the Examiner cites the luminal portion 18 and support portion 19 in Fig. 2A of Brown for including a base layer and a second layer covering the base layer. Applicant notes that Fig. 2A is an enlarged sectional view of a portion of the stent of Fig. 2, where the elongated member 12 includes a cavity 20 as a concave groove. The Examiner incorrectly shades the sectional half view of Fig. 2A to include a second layer covering the base layer; however, the Examiner is shading the same structural element 12 that is just taken in a sectional view of Fig. 2. And Brown's Fig. 2A includes an outer surface 16 with a luminal portion 18 for contacting the interior of the body lumen as shown in Fig. 2, which shows that luminal portion 18 is nothing more than a portion of a surface and not a base layer as the Examiner contends. And Fig. 2A's outer surface 16 includes a support portion 19 for supporting the walls 14 of the body lumen 13, as shown in Fig. 2. The support portion 19 is exactly that, a portion of the outer surface 16, where the support portion 19 could not be second layer covering the base layer. Finally, Figs. 2 and 2A of Brown is a concave groove with a single slit shaped opening 22, which does not show or teach a plurality of openings communicating with the internal cavity, as required by claim 16; therefore, the Examiner's comparison of Brown's Fig. 2A to Applicant's Figure 7 inappropriate and misplaced.

And the Examiner cites the luminal portion 18 and support portion 19 in Fig. 3 of Brown for including a base layer and a second layer covering the base layer. Again, the luminal portion

18 and support portion 19 are portions of a surface and not a base layer and a second layer, respectively. Any arbitrary line drawing through the helical stent 11' does not transform luminal portion 18 and support portion 19 into a second layer covering the base layer. Brown notes that the depth of the cavity 20 within the stent 11' is no more than half the cross-section diameter of the elongated member 12'. Brown, Col. 8, lines 14-17. The cross-section diameter of the elongated member 12' evinces more that the elongated member 12 does not include a separate base layer and second layer covering, as a layer does not have a cross-sectional diameter. Finally, Fig. 3 of Brown again shows an interior cavity 20 with a single slit opening 22, which does not teach or disclose a plurality of openings communicating with the internal cavity, as required by claim 16; therefore, the Examiner's comparison of Brown's Fig. 3 to Applicant's Figure 6 is inappropriate and erroneous.

Also, the Examiner cites the luminal portion 18 and support portion 19 in Fig. 6 of Brown for including a base layer and a second layer covering the base layer. Again, the luminal portion 18 and support portion 19 are portions of a surface and not a base layer and a second layer, respectively. Any arbitrary line drawing through the helical stent 11"" does not transform luminal portion 18 and support portion 19 into a second layer covering the base layer. Fig. 6 shows a plurality of openings 28 in only a portion of the circumference of the elongated member. Brown, Col. 9, lines 22-27. Again, a portion is not a layer, more so, a portion of a circumference is not a layer. Brown continues to elaborate on the plurality of holes in the circumference of the elongated member as occupying a specific percentage of the circumference of the elongated member. This gives guidance as to the portion of the circumference being a section of the wire, stand, or filament of the elongated member, and not a discrete layer.

And the Examiner cites the luminal portion 18 and support portion 19 in Fig. 8 of Brown for including a base layer and a second layer covering the base layer. Fig. 8 does not includes a luminal portion 18 and a support portion 18 but rather a stent 40 with a fluid inlet opening 48 allowing fluid to enter an osmotic agent 44 adjacent to a biologically active agent 23 in cavity 20. Fig. 8 continues to state that a plurality of holes located in only a portion of the circumference of the tubular member, and such portion of the circumference of the tubular member is not a second layer. Moreover, Fig. 8 does not teach or suggest that a void space is intermediate the base and second layers that is enclosed therebetween, because Fig. 8 includes a fluid inlet opening 48 to allow the fluid to enter the osmotic agent 44 causing it to swell. Brown, Col. 9, lines 43-46. As such, any comparison to Applicant's Fig. 6 is misplaced and in error.

In sum, in order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03; *In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974). The Examiner has failed to establish a *prima facie* case of obviousness with respect to Claim 16 because neither Brown nor Whicher, either alone or in combination, teach or suggest Claim 16's limitation of a base layer and a second layer covering the base layer. The Examiner's rejection is, therefore, improper. Applicant respectfully submits that independent Claim 16 is allowable over the art cited and of record. Furthermore, if an independent claim is nonobvious under 35 U.S.C. §103(a), the claims dependent therefrom are also nonobvious. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988). Claims 20, 26-28, and 30-37 depend from independent Claim 16 and, therefore, are also nonobvious over the art cited and of record.

B. Alternatively, Brown fails to disclose a void space intermediate the base and second layers that is enclosed therebetween

Even if Brown discloses an endoluminal stent comprising a base layer and a second layer covering the base layer, Brown does not disclose Claim 16's void space intermediate the base and second layers that is enclosed therebetween. The Examiner asserts that Brown discloses:

> [A] base layer (considered luminal surface or layer 18) and a second layer (considered abluminal surface or layer 19) covering the base layer (see figures 2A, 3, 6, 8 and attachments 2-5 which more clearly show location of "layers"), a void space (20) intermediate the layers and enclosed therebetween.

(Final Office Action mailed February 2, 2009, page 4). Contrary to the Examiner's assertion, Applicant submits that none of the embodiments illustrated Brown's in Figs. 2A, 3, 6, 8 show a void space 20 intermediate the (Examiner characterized) base and second layers that is enclosed therebetween.

"Intermediate" means lying or occurring in a middle position or state and "enclosed" means to be surrounded on all sides. (www.dictionary.com). In the Examiner's redrawing of Brown's Fig. 2A as shown in Attachment 2, the void space 20 is not "enclosed" by the (Examiner denoted) base and second layers because the void space 20 is not surrounded on all sides by the base and second layers. In the Examiner's redrawing of Brown's Figs. 3, 6, and 8 shown, respectively, in Attachments 5, 3, and 4, the void space 20 is not "intermediate" the (Examiner denoted) base and second layers because the void space 20 is not lying in a middle position between the base and second layers. Rather, the void space 20 in these figures is located

near the perimeter of the (Examiner denoted) second layer. Still further, in the Examiner's redrawing of Brown's Fig. 8 in Attachment 4, the Examiner inappropriately labels Brown's element 44 as a void space. Brown describes element 44 as an "osmotic agent" which may be an "osmagnet, an osmopolymer, or a mixture of the two" (col. 9, lines 46-48). Brown's osmotic agent 44 clearly is not the same as the void space required by Claim 16. As such, Brown is inappropriate for teaching or suggesting a void space intermediate the base and second layers that is enclosed therebetween.

In order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03; *In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974). The Examiner has failed to establish a *prima facie* case of obviousness with respect to Claim 16 because neither Brown nor Whicher, either alone or in combination, teach or suggest Claim 16's limitation of a void space intermediate the base and second layers that is enclosed therebetween. The Examiner's rejection is, therefore, improper. Applicant respectfully submits that independent Claim 16 is allowable over the art cited and of record. Furthermore, if an independent claim is nonobvious under 35 U.S.C. §103(a), the claims dependent therefrom are also nonobvious. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988). Claims 20, 26-28, and 30-37 depend from independent Claim 16 and, therefore, are also nonobvious over the art cited and of record.

C. Alternatively, Brown and Whicher fail to disclose a reason to combine their elements

Claim 16 requires that its structural elements be "vacuum deposited." The Examiner admits that Brown "does not disclose vacuum deposition metal to form the structural elements." (Final Office Action mailed February 2, 2009, page 4). However, the Examiner asserts that:

> Whicher teaches in the same field of endoluminal stents, a method of making a stent by using vacuum deposition techniques... [and it] would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Brown's endoluminal stent shape, with Whicher's method of manufacture (vacuum deposition) in order to provide a stent with improved material properties.

(Final Office Action mailed February 2, 2009, page 4). Even if Brown and Whicher, either alone or in combination, disclose every element of Claim 16, neither provides an apparent reason to combine the vacuum deposition techniques of Whicher with the endoluminal stent shape provided by Brown in the fashion claimed by Claim 16. In the **precedential** BPAI Decision *Ex parte Whalen*, the Board held that "obviousness cannot be proven merely by

showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some 'apparent **reason** to combine the known elements in the fashion claim.'" BPAI Appeal 2007-4423, p. 16 (July 23, 2008) (quoting *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007)), emphasis added. Moreover, the Board held that in the *KSR* decision "[t]he Court did not [ ] discard the TSM [teach-suggestion-motivation] test completely; it noted that its precedents show that an invention 'composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.'" *Ex parte Whalen*, BPAI Appeal 2007-4423, p. 15 (July 23, 2008) (quoting *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)). Accordingly, the Board held that the *KSR* decision requires:

> [T]hat the TSM test must be applied flexibly, and take into account a number of factors 'in order to determine whether there was an apparent **reason** to combine the known elements in the fashion claimed. Despite this flexibility, however, the Court stated that 'it can be important **to identify a reason** that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the way the new invention does.' 'To facilitate review, this analysis should be made **explicit**.'

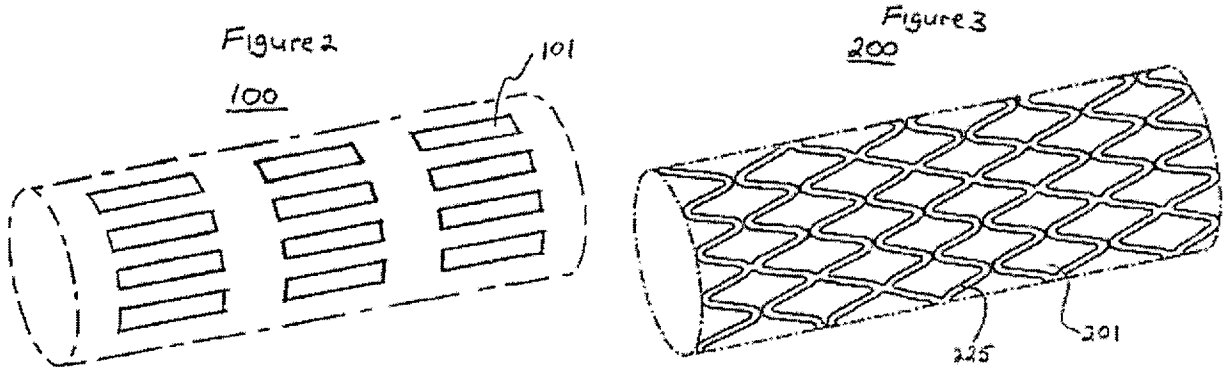
*Ex parte Whalen*, BPAI Appeal 2007-4423, p. 15 (July 23, 2008) (quoting *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)), emphasis added. Thus, even if the references cited, either alone or in combination, disclose all elements of the claimed invention, the *KSR* decision requires the Examiner to provide, with explicit analysis, a reason why it would have been obvious to combine the elements of the references in the way Claim 16 does.

Applicant submits that the Examiner has failed to provide an explicit analysis of the reason why it would have been obvious to combine the vacuum deposition techniques of Whicher with the endoluminal stent shape provided by Brown. Nowhere does Whicher teach such a reason to use vacuum deposition techniques to make the drug delivery stent, let alone the directional drug delivery stent as disclosed by Brown. The Examiner's trivial grounds to combine Brown with Whicher's method of manufacture to provide a stent with improved material properties is misplaced, because Whicher only mentions material properties of raw materials that affect the performance properties of a medical device. Whicher, Col. 1, lines 50-52. Brown references materials of the stent that the elongated member 12 that is preferably non-biodegradable. Such a non-biodegradable material has little to do with the performance properties of the materials discussed in Whicher. Consequently, even if Brown and Whicher, either alone or in combination, teach or suggest each of Claim 16's elements, the obviousness

rejection is improper, because the Examiner has not provided explicit analysis of why it would have been obvious to combine the elements of Brown and Whicher in the manner, fashion, or way of Claim 16.

D. Even if there is a reason to combine the elements in Brown and Whicher, such a hypothetical construct would not have been predictable to one of ordinary skill in the art at the time the invention was made

Moreover, even assuming *arguendo* that there was somehow a rationale for combining the teachings of Brown and Whicher and Brown and Whicher teach all the elements of Claim 16, there is still no evidence that such a hypothetical construct would be predictable, operable, and would still possess all the limitations recited in the pending claims. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 409, 82 USPQ2d 1385, 1396 (2007). As known to those in the vacuum deposition art, the final product produced by vacuum deposition is highly dependent on tightly controlled process parameters in the vacuum deposition process. By haphazardly combining the teachings of Brown and Whicher, where Whicher only teaches a distinctive set of process parameters distinct and different from that of the present application, the Examiner has created a hypothetically constructed device with no certainty or predictability as to whether the final device would include all of Brown's features or elements. For example, Whicher only teaches that a slotted metallic stent or a wire framed metallic stent may be formed by the vacuum deposition process, as shown in Figures 2 and 3 of Whicher, respectively and shown below:




Whicher merely teaches providing a substrate to serve as a target for source material by vapor deposition, providing a source for material for vapor deposition, the source material is

deposited as a metallic layer, and the metallic layer is removed from the substrate. Whicher, Col. 3, lines 26-50. Even though Whicher states that the configuration of the substrate may be selected according to the desired aspects of the medical device, the process parameters of Whicher will still only result in a singular medical device without a base layer and a second layer covering the base layer further comprising a void space intermediate the base and second layers that is enclosed therebetween, which is required by Claim 16. And Whicher only discloses depositing a single metallic layer to achieve a desired thickness and a range of crystalline morphologies (Whicher, Col. 7, lines 5-10), but nowhere in Whicher are there enabling guidelines to one of ordinary skill in the art to include a void space intermediate the base and second layers and a plurality of pores passing through the second layer and communicating with the void space. More so, Brown is silent as to any process parameters to configure or produce the Examiner's marked drawings of Figs. 2A, 3, 6, or 8, and the Examiner correctly indicates that Brown is silent to a manufacturing process to produce Figs. 2A, 3, 6, or 8. Any combination of Whicher's manufacturing process with Brown would result in a singular medical device without a void space intermediate the base and second layers and enclosed therebetween. As such, any combination of Brown and Whicher's deposition parameters would not be predictable to one of ordinary skill in the art to result in an obvious combination of Claim 16's elements.

To provide guidance and enablement for Claim 16, the present application states the following:

> Because, the internal cavities and openings must be formed during deposition, the vacuum deposition techniques must be modified to deposit requisite patterns of sacrificial material to form the regions of the internal cavities and openings, over a base layer of structural material, then depositing a second layer of structural material over the sacrificial material and the base layer. The sacrificial material may then be removed, such as by etching, to leave the internal cavities and plurality of openings formed within the deposited bulk material.

Present Application, Page 11, lines 8-13. Whicher is silent to any type of sacrificial layer to produce such internal cavities or void space between the base layer and a second layer. If one was to modify Brown with Whicher teachings, there is no predictability, or even evidence indicating that the hypothetically constructed device would still retain the all the limitations of Claim 16. The Examiner even states that Brown does <u>not</u> disclose any manufacturing methods to achieve the stated structure in the Figures disclosed by Brown. Page 6, ¶ 1 of Final Office Action dated February 26, 2009. If there is no enabling guidelines for Brown's device, one of ordinary skill in the art could not take the drawings of Brown, let alone the Examiner's

capricious redrawings of Brown's figures, and combine the detailed process parameters of Whicher to arrive at the applicant's invention as in Claim 16. Simply put, the Examiner reconstructed the Applicant's invention with hindsight and escaped the requirement of enabling such reconstruction. Similarly, if the modified Brown device was further manufactured to incorporate the teachings of Whicher (e.g., simple stent structure), there is also no predictability or evidence indicating that the resulting Whicher deposition process would still retain Brown's elements and features. Consequently, even if Brown and Whicher, either alone or in combination, teach or suggest each of Claim 16's elements, the obviousness rejection is improper, because neither Brown nor Whicher provides a teaching to one of ordinary skill in the art to arrive at the elements in the manner of Claim 16 with predictability or reliability.

Applicant respectfully submits that independent Claim 16 is allowable over the art cited and of record. Furthermore, if an independent claim is nonobvious under 35 U.S.C. §103(a), the claims dependent therefrom are also nonobvious. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988). Claims 20, 26-28, and 30-37 depend from independent Claim 16 and, therefore, are also nonobvious over the art cited and of record, and for additional reasons stated below.

## II. The Examiner's obviousness rejection of Claim 20 under 35 U.S.C. §103(a) is improper and should be withdrawn.

In order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03; *In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974). The Examiner has failed to establish a *prima facie* case of obviousness with respect to Claim 20 because neither Brown nor Whicher, either alone or in combination, teach or suggest Claim 20's limitation of a degradable plug.

Claim 20 requires "[T]he endoluminal stent according to claim 16, further comprising a degradable plug residing within the plurality of pores to prohibit release of the at least one bioactive agent until the degradation of the degradable plug." The Examiner argues that Brown discloses "a degradable plug (biodegradable matrix 27; shown in the cavities and extending into the pores, see Fig. 3, 9 for example; col. 8, lines 62 – col. 9, line 5). (Final Office Action mailed February 2, 2009, page 6).

Applicant respectfully disagrees that Brown's delivery matrix 27 is the same as Claim 20's biodegradable plug. To begin with, the Examiner incorrectly cites Brown's Figs. 3 and 9 as showing the delivery matrix 27 since only Fig. 4 of Brown shows the delivery matrix 27. Moreover, Brown states that "in Fig. 3, no delivery matrix 27 is needed." (Spec. col. 9, lines 6-

7). Nevertheless, even the delivery matrix 27 of Brown's Fig. 4 is not the same as Claim 20's biodegradable plug. Claim 20 requires that the biodegradable plug reside "within the plurality of pores." On the contrary, Brown's Fig. 4 (reproduced below) shows the delivery matrix 27 residing entirely within cavity 20.

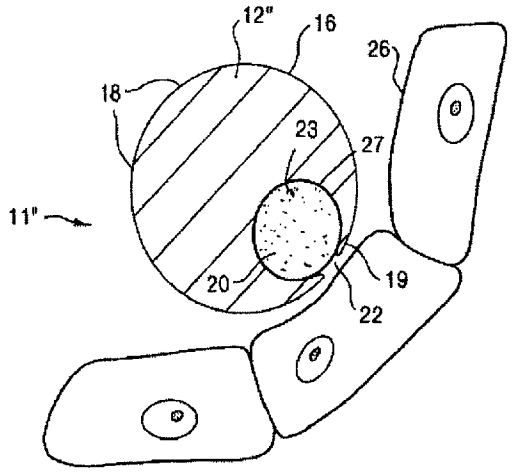



FIG. 4

Moreover, Brown's specification never states that the delivery matrix 27 resides within pores 22, but rather that cavity 20 contains the delivery matrix 27. (Col. 8, lines 62-67).

Even if one were to construe the delivery matrix 27 as residing within the pores 22, the delivery matrix is not a plug "to prohibit release of at least one bioactive agent until the degradation of the degradable plug" as required by Claim 20. The delivery matrix 27 of Brown permits elution of bioactive agents to the pores by a lattice-like structure and not by allowing material to degrade, so delivery matrix 27 has a completely different structure and mechanism of action such that it does not anticipate Claim 20.

Accordingly, the obviousness rejection of Claim 20 is legally insufficient given that Brown and Whicher's fail to teach or suggest, in combination, the claimed elements of "a degradable plug residing within the plurality of pores to prohibit release of the at least one bioactive agent until the degradation of the degradable plug."

## III. **The Examiner's obviousness rejection of Claim 26-27 under 35 U.S.C. §103(a) is improper and should be withdrawn.**

While the specifically claimed elements in each of Claims 26 and 27 are broader than the specific disclosure in the Brown or Whicher reference, Applicant acknowledges that if any element of a Markush claim is anticipated, then the entire claim is considered anticipated. *Ecolochem, Inc. v. Southern California Edison Co.*, 91 F.3d 169 (Fed. Cir. 1996); *In re Skoll*,

523 F.2d 1392, 1397, 187 USPQ 481, 484-85 (C.C.P.A. 1975). Since Claims 26 and 27 are framed as Markush claims, the patentability of Claims 26-27 are based upon the patentability of independent Claim 16, as discussed above.

Accordingly, the obviousness rejection for Claims 26-27 under 35 U.S.C. §103(a) is legally insufficient.

## IV. **The Examiner's obviousness rejection of Claim 28 under 35 U.S.C. §103(a) is improper and should be withdrawn.**

In order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03; *In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974). The Examiner has failed to establish a *prima facie* case of obviousness with respect to Claim 28 because neither Brown nor Whicher, either alone or in combination, teach or suggest Claim 28's limitation of a plurality of a plurality of independent internal cavities along the length of the structural elements.

Claim 28 requires "[T]he endoluminal stent according to claim 16, wherein the void space comprises a plurality of independent internal cavities along the length of the structural elements." The Examiner argues that Brown discloses "a plurality of independent cavities (each structural element 12 in the mesh stent may have its own cavity, thus plurality of cavities amongst all the structural elements 12; further, elements 12 are shown to have multiple cavities fig. 9 for example; further, at least one cavity is disclosed, encompassing more than one, col. 2, lines 59-61). (Final Office Action mailed February 2, 2009, page 6).

Applicant respectfully disagrees with the Examiner that Brown's cavities 20 in Fig. 9 are the same as Claim 28's plurality of independent internal cavities that extend along the length of the structural elements. The two cavities 20 in Brown's Fig. 9 are not independent because they do not exist free from control or restraint from each other. Furthermore, while Brown may disclose cavities that extend along the length of Brown's elongated member 12, Brown does not show or teach how a cavity is to exist independently from another cavity along the length of the elongated member 12.

Accordingly, the obviousness rejection of Claim 28 is legally insufficient given that Brown and Whicher's fail to teach or suggest, in combination, the claimed elements of "a plurality of independent internal cavities along the length of the structural elements."

## V. **The Examiner's obviousness rejection of Claim 30 under 35 U.S.C. §103(a) is improper and should be withdrawn.**

In order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03; *In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974). The Examiner has failed to establish a *prima facie* case of obviousness with respect to Claim 30 because neither Brown nor Whicher, either alone or in combination, teach or suggest Claim 30's limitation of a stent having at least one surface having controlled heterogeneities thereupon.

The Examiner equates "microstructure" with "heterogeneities" and therefore asserts that Whicher discloses controlling heterogeneities by vacuum deposition. (Final Office Action mailed February 2, 2009, pages 3 and 7). Additionally, the Examiner asserts that Whicher inherently discloses a stent having controlled heterogeneities since Whicher discloses the "same vacuum deposition processes (sputtering, ion beam deposition) and use of the same materials used by the applicant." (Final Office Action mailed February 2, 2009, page 6). Applicant submits that each of these two assertions is unwarranted and therefore the obviousness rejection of Claim 30 is improper. Furthermore, Applicant submits that Whicher is not enabling for any deposition process for controlled heterogeneities.

The Examiner cites to the Board Decision in related application 09/707,685 ("the '685 Board Decision") for the rationale that the Whicher reference was affirmed based on similar claim language. Final Office Action dated February 26, 2009 at p. 3. The Applicant respectfully notes that the '685 decision only whether Whicher's vacuum deposition process inherently minimizes the formation of chemical and intra- and inter-granular precipitates in the bulk material of an as-deposited crystalline film. Page 3, ¶ 3, the '685 Board Decision. The '685 Board Decision found no error in the Examiner's conclusion that Whicher anticipates the claim invention of the '685 application, based on the evidence of record. The Applicant submits that the Examiner inappropriately applied the reasoning in the '685 Board Decision because the evidence of record is different in the present application, as indicated below.

Claims 31-37 depend from independent Claim 30. These claims are allowable for the same reasons set forth with respect to their parent Claim 30 since each sets forth additional elements of Applicant's device. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious under 35 U.S.C. §103(a), the claims dependent therefrom are also nonobvious).

A. Whicher fails to disclose a stent having at least one surface having controlled heterogeneities thereupon, since controlling heterogeneities is not the same as controlling microstructure

On page 3 of the Final Office Action mailed February 2, 2009, the Examiner asserts:

> Whicher clearly discloses controlling properties of the material and its microstructure (heterogeneities) by the deposition process (col. 2, lines 6-10, 16-31; col. 3, lines 17-25). See also Board decision for related application 09/707,685 mailed on September 30, 2008 (common inventor, same assignee and same attorney of record) in which the Whicher reference was affirmed based on similar claim language.

Applicant recognizes that Whicher discloses using vacuum deposition for a surface's microstructure. However, Applicant submits that a surface having a controlled microstructure is not the same as a surface having controlled heterogeneities. Support for the vacuum deposition techniques described in Applicant's specification can be found in U.S. Patent Application Serial No. 09/443,929 (now U.S. Patent No. 6,379,383 hereinafter "the '383 patent") which is incorporated by reference. (Present Application, page 11, lines 4-8). The '383 patent relates to "an endoluminal stent which is made of a material having controlled heterogeneities along the blood flow surface of the stent." ('383 patent, Abstract; col. 4, lines 41-48). The '383 patent describes shortcomings associated with prior art stents being:

> [P]rior art stents employ coatings applied to stents fabricated in accordance with conventional stent formation techniques, e.g., cold-forming metals, the underlying stent substrate is characterized by uncontrolled heterogeneities on the surface thereof. Thus, coatings merely are laid upon the heterogeneous stent surface, and inherently conform to the heterogeneities in the stent surface and mirror these heterogeneities at the blood contact surface of the resulting coating. This is conceptually similar to adding a coat of fresh paint over an old coating of blistered paint, the fresh coating will conform to the blistering and eventually, itself, blister and delaminate from the underlying substrate.

(Col. 4, lines 1-13). In one embodiment, the '383 patent solves this problem by using vacuum deposition to add a layer of material with controlled heterogeneities to a surface of stent substrate having uncontrolled heterogeneities so to attain a stent having desired surface properties. (See, e.g., col. 5, lines 33-53 and Example 1). Furthermore, the '383 patent states that "[t]he heterogeneities which are controlled in the present invention include: grain size, grain phase, grain material composition, stent-material composition, and surface topography." (Col. 4, lines 44-47). Thus, according to the '383 patent, a surface with controlled heterogeneities has different grain sizes, grain phases, etc. such that when the surface is added to an object having

uncontrolled heterogeneities, the result is a new surface having controlled heterogeneities and desired material properties.

On the contrary, Whicher merely describes using vacuum deposition for the microstructure of a layer that is added to a substrate. (Whicher spec. col. 2, lines 17-23). Like the prior art stents described in the '383 patent (discussed above), the controlled microstructure of this layer conforms to the uncontrolled heterogeneities of the substrate when the layer is placed upon the substrate. This is similar to the metaphor discussed in the '383 patent of a fresh coating of paint conforming to blisters of an underlying coating of paint. (Col. 4, lines 10-14). The result of the process described by Whicher is that a new surface, formed by the combination of the controlled microstructure layer and the substrate with uncontrolled heterogeneities, will have uncontrolled heterogeneities. Thus, Whicher does not disclose a stent surface having controlled heterogeneities thereupon as required by Claim 30.

In regards to the Examiner's citation of the "Board decision for related application 09/707,685 mailed on September 30, 2008" (i.e. *Ex parte Palmaz*, Appeal 2008-1316 (September 29, 2008), the Board did not address whether Whicher disclosed a stent surface having controlled heterogeneities thereupon. Rather, the Board merely held that Whicher's vacuum deposition process inherently controls the formation of precipitates. *Ex parte Palmaz*, Appeal 2008-1316, pg. 11 (September 29, 2008).

In order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03; *In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974). The Examiner has failed to establish a *prima facie* case of obviousness with respect to Claim 30 because neither Brown nor Whicher, either alone or in combination, teach or suggest Claim 30's limitation of a stent having at least one surface having controlled heterogeneities thereupon. The Examiner's rejection is, therefore, improper. Applicant respectfully submits that independent Claim 30 is allowable over the art cited and of record. Furthermore, if an independent claim is nonobvious under 35 U.S.C. §103(a), the claims dependent therefrom are also nonobvious. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988). Claims 31-37 depend from independent Claim 30 and, therefore, are also nonobvious over the art cited and of record.

B. Whicher fails to inherently disclose a stent having at least one surface having controlled heterogeneities thereupon

On page 3 of the Final Office Action mailed February 2, 2009, the Examiner asserts:

> Whicher's method inherently controls the stents heterogeneities, because Whicher discloses the same vacuum deposition processes (sputtering, ion beam deposition) and use of the same materials used by the applicant. Applicants disclose in their specification that it is the vacuum deposition process that controls the heterogeneities. Since Whicher is using the same process as the applicant, Whicher is inherently "controlling heterogeneities" just as much as the applicant is.

Applicant respectfully disagrees with the Examiner and asserts that Examiner has failed to come forth with evidence that Whicher's process controls heterogeneities as required by MPEP §2112. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Whicher is silent as to the deposition processes that include or result in controlled heterogeneities. Moreover, the Examiner's assertion that the combination of vacuum deposition and the materials used by Applicant *per se* results in controlled heterogeneities is baseless. On the contrary, vacuum deposition techniques must be used in a specific manner in combination with certain process parameters in order to achieve controlled heterogeneities as described in U.S. Patent Application Serial No. 09/443,929 (now U.S. Patent No. 6,379,383) which is incorporated by reference in Applicant's specification. (Page 11, lines 4-8). The '383 patent discloses several examples of sputtering and ion beam assisted evaporative deposition, including specific process parameters, as to result in controlled heterogeneities. For sputtering, the '383 patent states that:

> The deposition chamber is evacuated to a pressure less than or equal to $2x10^{-7}$ Torr. Pre-cleaning of the substrate is conducted under vacuum by glow discharge. The substrate temperature is controlled to achieve a temperature between about 300 and 1100 degrees Centigrade. A bias voltage between-1000 and +1000 volts is applied to the substrate sufficient to cause energetic species arriving at the surface of the substrate to have a hyperthermal energy between 0.1 eV and about 700 eV, preferably between 5-50 eV. The deposition sources are circumferential and are oriented to deposit from the target circumferentially about the substrate. During deposition, the deposition pressure is maintained between 0.1 and 10 mTorr. A

> sacrificial carbon layer of substantially uniform thickness (+/- 5%) between 10 and 500 Angstroms is deposited circumferentially on the substrate. After depositing the carbon layer, a cylindrical film of stainless steel is deposited onto the sacrificial carbon layer on the cylindrical substrate at a deposition rate between about 10 to 100 microns/hour.

'383 patent, Col. 7, lines 8-29. After removing the carbon intermediate layer, the film is removed from the substrate and exhibits surface properties characterized by controlled heterogeneities in grain size, material composition and surface topography. '383 patent, Col. 7, lines 33-38. On the contrary, Whicher states the following process parameters for sputtering:

> The chamber is evacuated to $10^{-3}$ -$10^{-5}$ Pa, and backfilled with an inert gas such as argon to a pressure of 0.1-10 Pa to sustain a plasma discharge.

Whicher, Col. 4, lines 15-18. These are the only process parameters that Whicher discloses for sputtering, and such process parameters are silent as to controlling heterogeneities. Moreover, the '383 patent provides for a bias voltage between -1000 and +1000 volts to cause energetic species arriving at the substrate to have a hyperthermal energy between 0.1 eV and about 700 eV, while Whicher is silent to a bias voltage or a hyperthermal energy. And the '383 patent provides for a substrate temperature between 300 and 1100 degrees Centigrade and a deposition rate between about 10 to 100 microns/hour, while Whicher is silent to a substrate temperature and a deposition rate. As such, Whicher discloses remarkably different sputtering deposition parameters, which do not allow one of ordinary skill in the art to arrive at a surface having controlled heterogeneities thereupon, and more so, do not inherently produce a surface having controlled heterogeneities thereupon.

Applicant notes that the general art of vacuum deposition includes numerous deposition technologies, including sputtering, ion-beam assisted evaporative deposition, cathodic arc, laser ablation, and direct ion beam deposition. Present Application, Col. 5, line 55 – Col. 6, line 14. And even within sputtering deposition, there are several sputtering techniques, including ion beam and plasma discharge. Whicher, Col. 4, lines 11-14. For the Examiner to surmise that Whicher inherently produces controlled heterogeneities since such control over properties are characteristic of such a process, the Examiner extremely generalizes the field of vacuum deposition without providing sufficient details or teachings as how one of ordinary skill in the art would control heterogeneities in sputtering, ion-beam assisted evaporative deposition, cathodic arc, laser ablation, direct ion beam deposition, or the sub-classes of sputtering. Any such control of Whicher's processes is not characteristic of controlling heterogeneities, because Whicher's

control is remarkably different and in stark contrast to the Applicant's specific vacuum deposition processes to control heterogeneities. As such, Whicher is inappropriate to inherently produce controlled heterogeneities as to render Claim 30 obvious.

In order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03; *In re Royka*, 490 F.2d 981, 982 (C.C.P.A. 1974). The Examiner has failed to establish a *prima facie* case of obviousness with respect to Claim 30 because neither Brown nor Whicher, either alone or in combination, teach or suggest Claim 30's limitation of a stent having at least one surface having controlled heterogeneities thereupon. The Examiner's rejection is, therefore, improper. Applicant respectfully submits that independent Claim 30 is allowable over the art cited and of record. Furthermore, if an independent claim is nonobvious under 35 U.S.C. §103(a), the claims dependent therefrom are also nonobvious. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988). Claims 31-37 depend from independent Claim 30 and, therefore, are also nonobvious over the art cited and of record.

C. Whicher is not enabling for any deposition process for controlled heterogeneities

According to the Federal Circuit, "[t]o serve as an anticipating reference, the reference must enable that which it is asserted to anticipate." *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. And Research*, 345 F.3d 1051, 1054 (Fed. Cir. 2003), emphasis added. In other words, in order "[t]o anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." *PPG Indus. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996), emphasis added.

In the pending matter, Whicher does not disclose a stent having a surface with controlled heterogeneities thereupon, let alone enable those skilled in the art to use vacuum deposition to control heterogeneities. None of the examples in Whicher contain any statements or suggestions that the vacuum deposited film is controlled for heterogeneities. For these reasons, Applicant submits that pending claims 30-37 are distinguished from the references cited and of record.

**Summary**

An obviousness rejection under 35 U.S.C. §103(a) requires that the cited prior art references must disclose each and every claimed element. Neither Brown nor Whicher, either alone or in combination, teach or suggest every limitation recited in the pending claims on

appeal. The cited references do not render the pending claims obvious, and the Examiner's rejection is improper. Accordingly, Applicant submits that pending claims 16, 20, 26-27, and 30-37 are patentable over the art cited and of record.

Respectfully submitted,

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September 28, 2009

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## 8. Claims Appendix

The following is a listing of the claims on appeal.

Claim 16. An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of vacuum deposited structural elements forming a radially expandable cylindrical member, the plurality of structural vacuum deposited elements including a complex finished geometry, each of the plurality of vacuum deposited structural elements having a wall thickness; wherein the vacuum deposited structural elements are fabricated of a metal and comprise a base layer and a second layer covering the base layer, further comprising a void space intermediate the base and second layers that is enclosed therebetween;

a plurality of pores passing through the second layer and communicating with the void space such that the void space is open only through the plurality of pores; and

at least one bioactive agent retained within the void space and elutable through the plurality of pores.

Claim 20. The endoluminal stent according to claim 16, further comprising a degradable plug residing within the plurality of pores to prohibit release of the at least one bioactive agent until the degradation of the degradable plug.

Claim 26. The endoluminal stent according to claim 16, wherein the metal is selected from the group consisting of titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, including zirconium-titanium-tantalum alloys, nitinol, and stainless steel.

Claim 27. The endoluminal stent according to claim 16, wherein the bioactive agent further comprises a pharmacologically active agent selected from the group consisting of antibiotic drugs, antiviral drugs, neoplastic agents, steroids, fibronectin, anti-clotting drugs, anti-platelet function drugs, drugs which prevent smooth muscle cell growth on inner surface wall of vessel, heparin, heparin fragments, aspirin, coumadin, tissue plasminogen activator, urokinase, hirudin, streptokinase, antiproliferatives, methotrexate, cisplatin, fluorouracil, adriamycin, antioxidants, ascorbic acid, beta carotene, vitamin E, antimetabolites, thromboxane inhibitors, non-steroidal and steroidal anti-inflammatory drugs, immunosuppresents, such as rapomycin, beta and calcium channel blockers, genetic materials including DNA and RNA fragments, complete expression genes, antibodies, lymphokines, growth factors, vascular endothelial growth factor and fibroblast growth factor, prostaglandins, leukotrienes, laminin, elastin, collagen, nitric oxide, and integrins.

Claim 28. The endoluminal stent according to claim 16, wherein the void space comprises a plurality of independent internal cavities along the length of the structural elements.

Claim 30. The endoluminal stent according to claim 16, wherein the metal of the first and second layers has at least one surface thereof having controlled heterogeneities thereupon.

Claim 31. The endoluminal stent according to claim 30, wherein the controlled heterogeneities are selected from the group consisting of grain size, grain phase, grain material composition and surface topography.

Claim 32. The endoluminal stent according to Claim 30, wherein the controlled heterogeneities define polar and non-polar binding sites for binding blood plasma proteins.

Claim 33. The endoluminal stent according to Claim 30, wherein the controlled heterogeneities are dimensioned to have a blood contact surface area substantially similar in size as endothelial cell surface integrin clusters.

Claim 34. The endoluminal stent according to Claim 30, wherein the controlled heterogeneities define cell-adhesion domains having interdomain boundaries less than the surface area of a human endothelial cell.

Claim 35. The endoluminal stent according to Claim 30, wherein the controlled heterogeneities form binding domains having a repeating pattern with no more than about 2 μm border to border spacing between adjacent binding domains.

Claim 36. The endoluminal stent according to Claim 30, wherein the controlled heterogeneities are dimensioned to have a blood contact surface area of about less than 6 $\mu m^2$.

Claim 37. The endoluminal stent according to Claim 30, wherein the controlled heterogeneity has a blood contact surface less than or equal to about 10 μm and an inter-heterogeneity boundary between about 0 and 2 μm.

## 9. Evidence Appendix

The following is Attachments 1-5 which the Examiner referenced in the Final Office Action mailed February 2, 2009.

Attachment #1 (marked up) applicants figs.

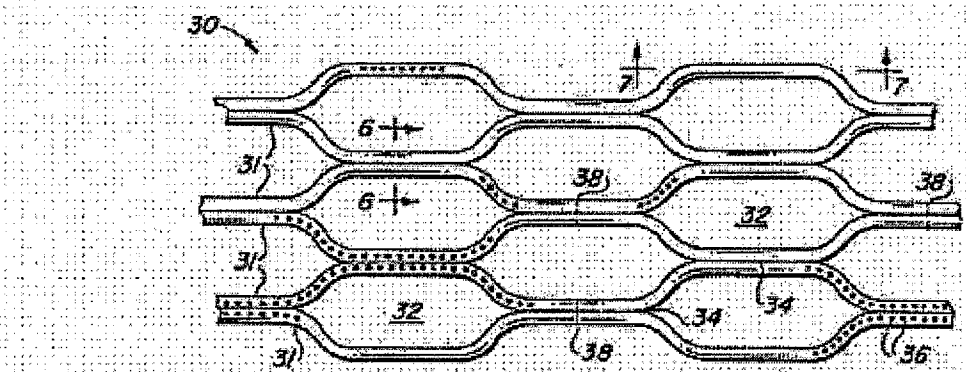


Fig. 5

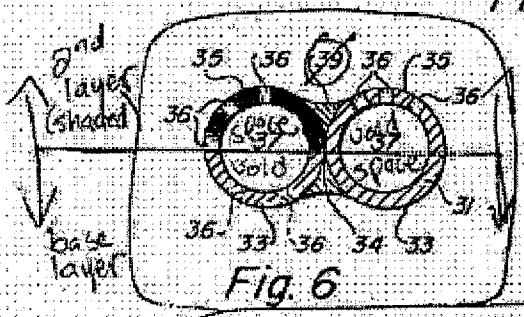


Fig. 6

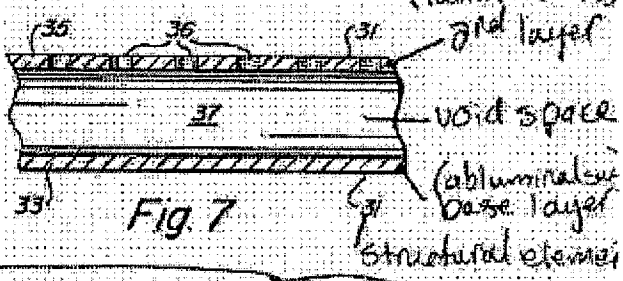


Fig. 7

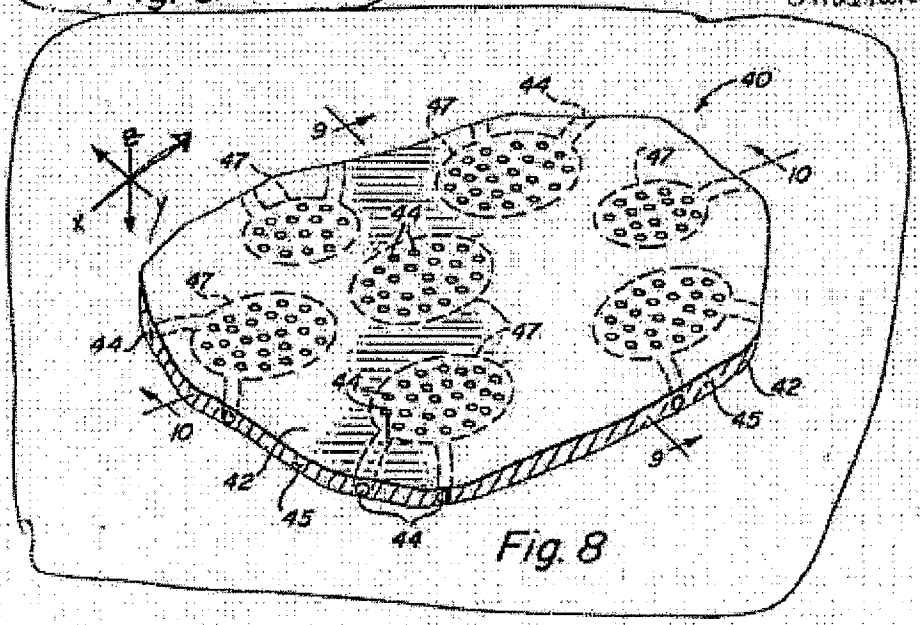


Fig. 8

Attachment #2 (marked up) - Brown.

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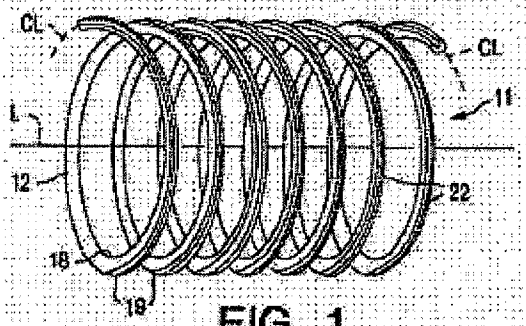


FIG. 1

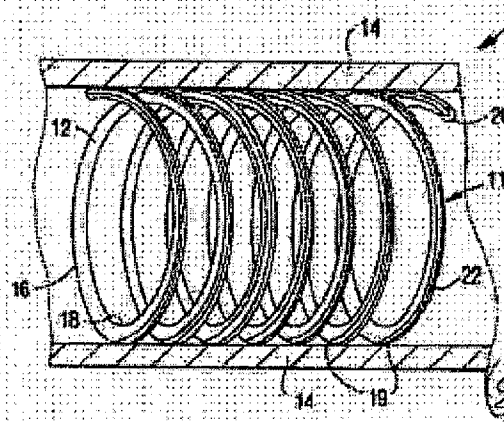


FIG. 2

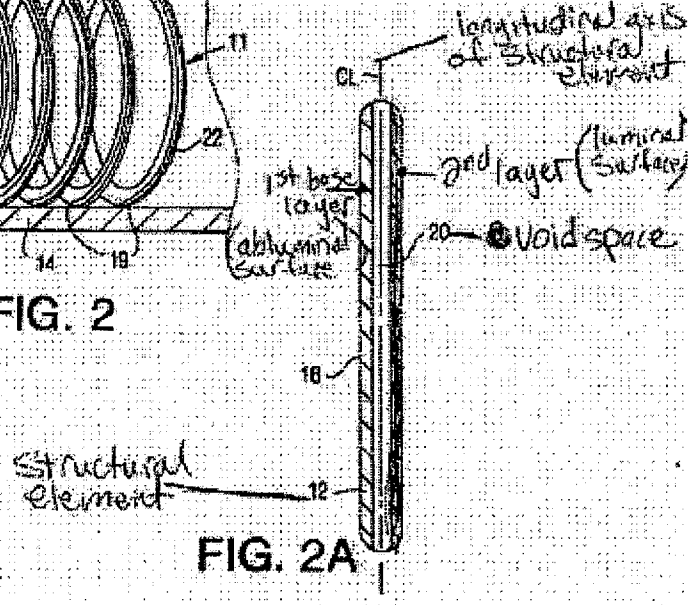


FIG. 2A

* compare to figure 7 of applicants specification.

7/24/08, EAST Version: 2.2.1.0

Attachment #3 (marked up) Brown

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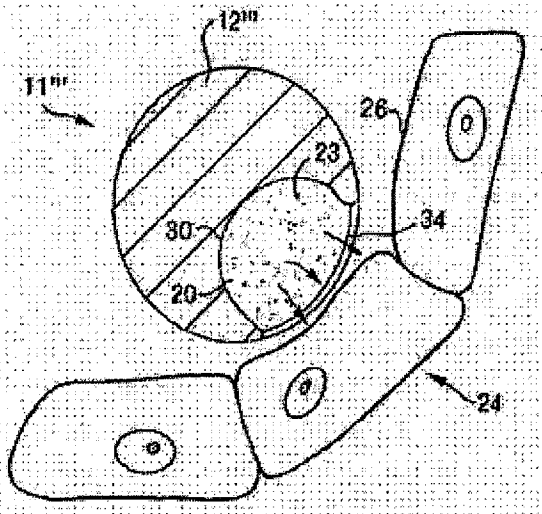



FIG. 5

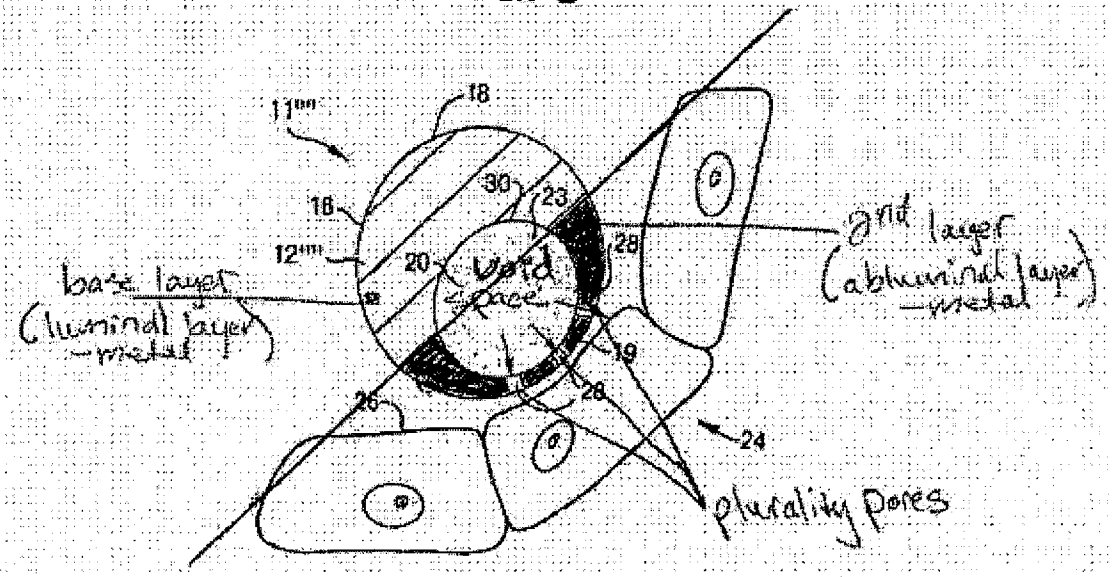



FIG. 6

* Compare to Figure 6 of applicants specification

7/24/08, EAST Version: 2.2.1.0

Attachment # 4 (marked up) - Brown

U.S. Patent Jun. 6, 2000 Sheet 4 of 8 6,071,305

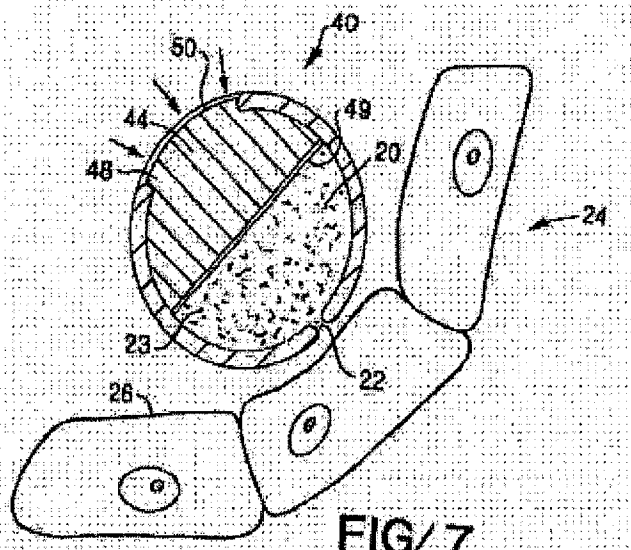



FIG. 7

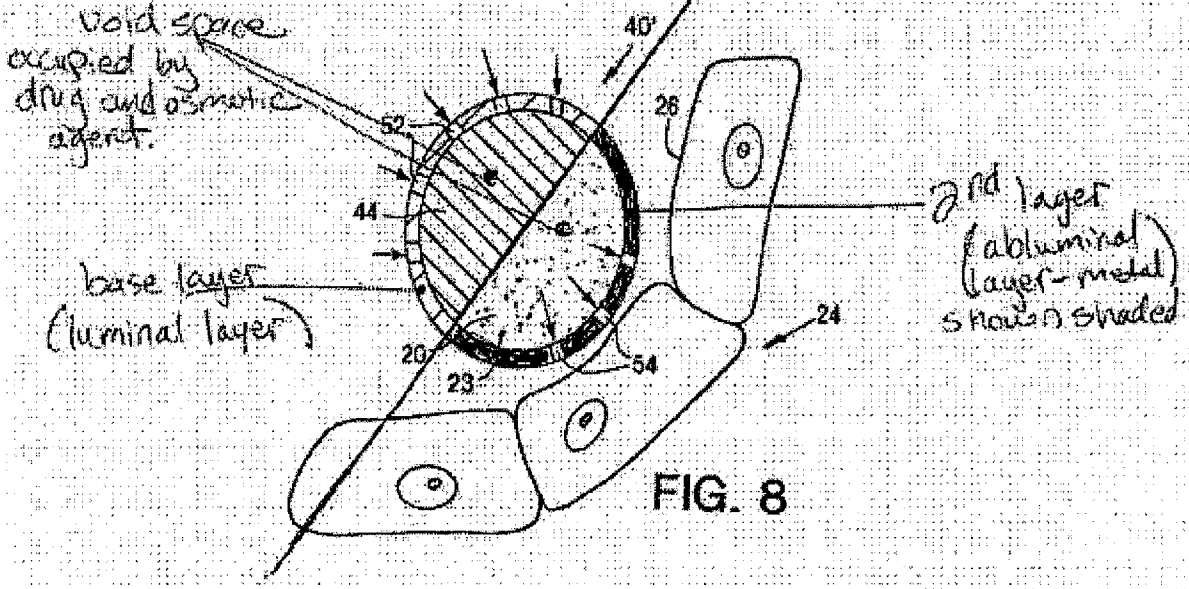


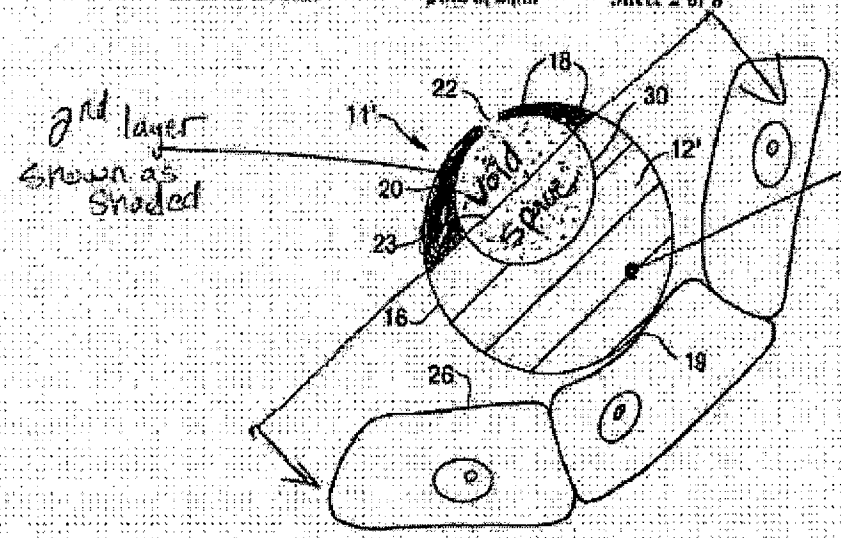

FIG. 8

* compare to figure 6 of applicants specification

7/24/06, EAST Version: 2.2.1.0

Attachment # 5 (marked up) - Brown






* compare to figure 6 of applicants specification

FIG. 3

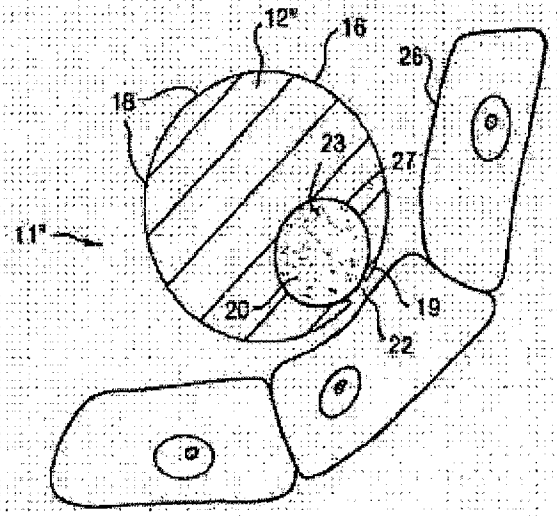



FIG. 4

7/24/09, EAST Version: 2.2.1.0

## 10. Related Proceedings Appendix

Copies of Board Decision in present application 09/716,146 decided on April 30, 2008, Appeal No. 2007-3212, Board Decision for related U.S. Application 09/707,685 decided on September 29, 2008, Appeal 2008-1316 (hereinafter the '685 Board Decision"), Board Decision for related U.S. Application 09/783,633 decided on February 21, 2008, Appeal No. 2008-0216, Board Decision for related U.S. Application 10/672,695 decided on March 31, 2009, Appeal No. 2008-5417, and Board Decision for related U.S. Application 10/258,087 decided on December 22, 2008, Appeal No. 2008-1062, are attached herewith.